

REMARKS / ARGUMENTS

This amendment is submitted in full response to the outstanding Office Action dated September 3, 2008 wherein claims 2-4, 9, 10 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Morita (U.S. Patent No. 5,628,765). In addition, claims 7, 11 and 12 stand rejected under 35 U.S.C. 103(a), as being unpatentable over Morita in view of Czernecki et al. (U.S. Patent No. 5,356,420).

Applicant wishes to thank the Examiner for his conscientious and detailed review of the claims of this application as presented in the amendment to this application filed on June 24, 2008. As a result, Applicant now further amends this application to overcome any inconsistencies and informalities in the recitation of the previously presented claims. Accordingly, Applicant's invention as now defined in the amended claims submitted herewith is believed to be include specific structural features which are not found or suggested the references of record to Morita and Czernecki et al., whether these references are considered either singularly or in combination with one another. Therefore, the outstanding rejections are respectfully traversed.

Applicant's Claimed Invention.

As now defined in amended independent claim 9 of this application, Applicant's invention comprises a lancet device including a housing having an at least partially open interior and a lancet 40 including a piercing tip 42 both of which are movably disposed within the open interior of the housing. Further, a biasing assembly includes a biasing element 50 disposed between one end of the housing and the lancet 40 as represented throughout the Figures of this application, specifically including, but not limited to, Figures 3 and 6. Applicant further defines this invention as including a cocking seat 30 movable with the lancet 40 towards said biasing element 50 when it is intended to position the lancet 40 in a "cocked" or ready to fire orientation. In addition, Applicant's claimed invention calls for an engagement assembly including an engagement member 45 mounted on the lancet 40.

The engagement assembly further includes a retention member 34 connected to the cocking seat 30 and movable therewith relative to the lancet 40. Further, the retention member 34 and the engagement member 45 are at least initially disposed in removable engagement with one another and are collectively structured to releasably connect the cocking seat 30 and the

lancet 40. Also, the engagement member 45 is removably connected to the lancet 40 and is structured for detachment from said lancet 40 and removal from the retention member 34 upon interruptive engagement between the engagement member 45 and a release element 56. The release element 56 is thereby disposable into releasing engagement with the engagement member 45 and cooperatively structured therewith to disconnect the engagement member 45 from said retention member 34 and disengage the cocking seat 30 from said lancet 40. Further, the biasing element 50 is disposed into biasing engagement with the lancet 40 and the piercing tip 42 so as to move the lancet 40 and piercing tip into a firing orientation upon disengagement between the lancet 40 and the cocking seat 30.

As now defined in dependent claims 11 and 12, Applicant's invention comprises a single use pivot 46, disclosed in Figures 3 and 6, which is used to removably interconnect the engagement member 45 to a remainder of the lancet 40. Further, the single use pivot is more specifically defined by a breakable hinge disposed in removable interconnecting relation between the engagement member 45 and the remainder of the lancet 40 to which it is connected.

References of Record to Morita.

As set forth above, the Examiner relies on Morita in support of the outstanding rejection under 35 U.S.C. 102(b) as such the Examiner contends that Morita discloses a lancet device having a housing 16 with an open interior and a piercing tip 44. Further, the Examiner interprets Morita as including a biasing assembly 54 disposed within the housing 16 and a cocking seat 34 movable with (when carried or transported) and relative to (when fired) the lancet. The Examiner further interprets Morita as including an engagement assembly 48 that engages the cocking seat 34 to hold against the force of the biasing assembly 54 as apparently represented in Figures 2 and 13 of Morita. In addition, the Examiner contends that Morita discloses a release element 68 that engages the engagement element 48 to release it from the cocking seat 34. When so released, the force of the biasing assembly 54 moves the lancet into the fired orientation.

In addition, on pages 2 and 3 of the outstanding Office Action, the Examiner specifically states that Morita discloses the cocking seat 34 remaining stationary relative to the housing and the release element being actuated from the exterior, as at 42. Additional structural features attributed to the Morita reference, by the Examiner, includes the engagement assembly

having an engagement member 48A mounted on the lancet in releasable engagement with the cocking seat 34. Finally, the Examiner contends that the engagement assembly further comprises a retention member 46 that can move with and relative to the lancet.

Applicant respectfully contends that Examiner's interpretation of the Morita structure is at least partially confusing based on the lack of a specific designation of the structure "the lancet" as applied by the Examiner in support of the outstanding rejection under 35 U.S.C. 102. The Examiner clearly states that structure 46 is the retention member and therefore does not consider member 46 "the lancet". As such the Examiner contends that the retention member 46 can move with and relative to "the lancet". Therefore it would appear that the retention member 46 is connected to or considered a part of "the lancet". Accordingly is not understood how the retention member 46 of Morita can move relative to "the lancet", at least in terms of the corresponding recited features of Applicant's claimed invention. **It is emphasized that Applicant's retention member 34 is defined as being connected to the cocking seat 30 and movable therewith relative to the lancet 40.** Clearly the retention member 46 of Morita is not connected to cocking seat

34, which is a part of the cover 16. Moreover, the retention member 46 could not be connected to the cocking seat 34 since such a structure could render the Morita device inoperable.

Independent claim 9 has been further amended to specifically recite that the retention member 34 and said engagement member 45 being disposed in removable engagement with one another so as to releasably connect the cocking seat 30 and the lancet 40. In Morita, as applied by the Examiner, the retention member 46 is not disposed in removable engagement with the engagement member 48A but may be considered an integral or fixed part therewith. Again, Applicant emphasizes that the retention member 34, as recited in the claims of this application, is connected to the cocking seat 30 and movable therewith relative to the lancet 40. As such, Applicant contends that the claims of this application now define the subject invention to include structural features clearly absent from the Morita reference.

References of Record to Morita and Czernecki et al. considered in Combination.

In addition, independent claim 9 as well as dependent claims 10 and 11 call for engagement member 45 being removably

connected to the lancet 40 and structured for detachment from said lancet 40 and removal from the retention member 34 upon interruptive engagement between the engagement member 45 and the release member 56.

The Examiner recognizes that Morita is absent the above noted structural features of Applicant's invention directed to the removable connection of the engagement member 45 with a remainder of the lancet 40. Accordingly, the Examiner relies on the Morita and Czernecki et al. combination, wherein Czernecki et al. discloses breakable retaining wings 11 which break to prevent reuse of the device. In light of this combination, the Examiner contends that it would have been obvious to one of ordinary skill in the art to make the engagement element 44A of Morita breakable as taught by Czernecki et al. to prevent use of the Morita device.

Applicant respectfully disagrees with the Examiner's contention. The claims defining Applicant's invention call for the inclusion of a single use pivot removably interconnecting the engagement member 45 to a remainder of the lancet 40. as such the single use pivot further comprises a breakable hinge disposed in removable interconnecting relation between the engagement member 45 and a remainder of the lancet 40. The

retention wings 11 of the Czernecki et al. reference are not connected to an engagement member. As such, wings do not serve to interconnect an engagement member to a remainder of the lancet. The wings 11 of Czernecki are a part of the piston or plunger 5 and are disposed or broken into an orientation where the piston 5 is no longer retained in its pre-fired orientation as represented in Figure 1.

Therefore, Applicant contends that the combination of Czernecki et al., **showing the broad feature of breakable wings** and Morita, **which does not require or suggest the use of any type of breakable structure**, does not constitute a viable combination sufficient to render Applicant's specifically recited structural features, obvious. **Applicant is not trying to protect, through claim language, the broad concept of a breakable structure.** To the contrary the specifically recited features of Applicant's invention call for an engagement member 45 removably connected to the lancet 40 and being structured for detachment of the engagement member 45 from a remainder of the lancet 40 and a separation of the engagement member 45 from the retention member 34, upon interruptive engagement between the engagement member 45 and the release member 56.

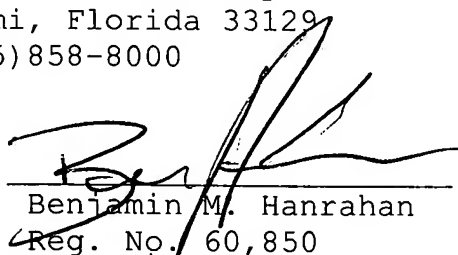
Conclusion.

Based on the above amendments and remarks reconsideration of this application is hereby requested. It is believed that this application is now in condition for allowance and such action is respectfully requested.

In addition, a request for an appropriate extension of time is enclosed herewith along with the corresponding PTO fee. In the event that any additional fee may be required by the filing of this paper, the Commissioner is hereby authorized to charge any fees and/or credits to our **Deposit Account No. 13-1227.**

Respectfully Submitted,

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